



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,506	09/17/2003	Rachel Meyers	MPI00-079P1RCP2CN1M	6793

30405 7590 05/12/2005

MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER

PAK, YONG D

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,506

Applicant(s)

MEYERS ET AL.

Examiner

Yong D. Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-19, 23-28, 35, 36 and 43-48 is/are pending in the application.
- 4a) Of the above claim(s) 16-19, 23-28, 35 and 36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43-45 and 47 is/are allowed.
- 6) ☒ Claim(s) 13-15 and 46 is/are rejected.
- 7) ☒ Claim(s) 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/17/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of 10/09/838,561, now issued as U.S. Patent No. 6,627,426.

The preliminary amendment filed on March 28, 2005, canceling claims 1-12, 20-22, 29-34 and 37-42, amending claims 13-14 and adding claims 43-48, has been entered.

Claims 13-19, 23-28, 35-36 and 43-48 are pending. Claims 16-19, 23-28 and 35-36 are withdrawn. Claims 13-15 and 43-48 are under consideration.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 13-15 and 43-48, drawn to a dehydrogenase, classified in class 435, subclass 190.
- II. Claims 16 and 19, drawn to an antibody against the dehydrogenase of Invention I, classified in class 530, subclass 387.9
- III. Claims 17-18, drawn to a method of detecting the presence of the dehydrogenase of Invention I, classified in class 435, subclass 26.
- IV. Claim 23-24 drawn to a method for identifying a compound with binds to the dehydrogenase of Invention I, classified in class 514, subclass 789.
- V. Claims 25, drawn to a method for modulating the activity of the dehydrogenase of Invention I, classified class 435, subclass 26.

Art Unit: 1652

- VI. Claims 26-27 and 35, drawn to a method for identifying compounds which modulate the activity of the dehydrogenase of Invention I, classified in class 514, subclass 789.
- VII. Claim 28, drawn to a method for identifying compounds which modulate virus activity, classified in class 435, subclass 235.1.
- VIII. Claim 36, drawn to a method for identifying compounds which modulate cellular proliferation, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Group I and the antibody of Group II are patentably distinct for the following reasons:

While the inventions of both Group I and Group II are polypeptides, in this instance the polypeptide of Group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of Group II encompasses antibodies. Thus the polypeptide of Group I and the antibody of Group II are structurally distinct molecules; any relationship between a polypeptide of Group I and an antibody of Group II is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of Group I is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of Group II is defined in terms of its binding specificity to a small structure within SEQ ID

Art Unit: 1652

NO: 5. Thus immunization with the polypeptides of Group I would result in the production of antibodies outside the scope of Group II.

Furthermore, searching the inventions of Group I and Group II would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group II. Furthermore, antibodies which bind to an epitope of a polypeptide of Group I may be known even if a polypeptide of Group I is novel. In addition, the technical literature search for the polypeptide of Group I and the antibody of Group II are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

Inventions I and Inventions III-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention I can be used for the production of antibodies against the protein. Searching the inventions of Groups I and III-VIII together would impose serious search burden. The inventions of Groups I and III-VIII have a separate status in the art as shown by their different classifications. Moreover, even if the polypeptide product were

Art Unit: 1652

known, the methods of Groups III-VIII may be novel and unobvious in the view of the preamble or active steps.

Inventions III-VIII are unrelated because the specification does not disclose that these methods would be used together. The methods are divergent in steps and have different modes of operation. Each invention performs this function using structurally and functionally divergent material. Further, the distinct steps require separate and distinct searches. As such, it would be burdensome to search Inventions III-VIII together.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VII or VII, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Ms. Schray on March 8, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 13-15 and

Art Unit: 1652

43-48 (Group II, claims 13-15 prior to the preliminary amendment filed on March 23, 2005). Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-19, 23-28 and 35-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Information Disclosure Statement

Art Unit: 1652

The information disclosure statement (IDS) submitted on September 17, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Specification

The disclosure is objected to because of the following informalities:

Examiner notes that applicants have not updated the relationship of the instant application to its parent application (09/838,561, 09/816,760 and 09/634,955) that has matured into a US patent (U.S. Patent No. 6,627,423, U.S. Patent No. 6,661,555 and U.S. Patent No. 6,511,834). Examiner urges applicants to amend said information by providing the US patent number in response to this Office action.

~~Applicant is required to comply with the sequence rules by inserting the~~
sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that the sequences in Figures 4, 9, 14 and 20 lack sequence identification numbers. See particularly 37 CFR 1.821(d). Appropriate correction is required.

Art Unit: 1652

The specification also contains blank spaces for ATCC Accession Numbers, for example on page 31. Appropriate correction is required.

Claim Objections

Claim 48 is objected to because of the following informalities: claim 48 is missing a period after "sequences". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 and claims 14-15 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, the phrase "under stringent conditions" is unclear. The metes and bounds are not clear in the context of the claims. The specification contains several hybridization conditions and depending on the hybridization condition, different nucleic acid sequences hybridize to a polynucleotide sequence. Therefore, it is not clear to the Examiner as to what hybridization conditions and polynucleotides are encompassed in the phrase.

Art Unit: 1652

Claim 13 and claims 14-15 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 appears to recite a Markush Group but lacks the conjunction "and". Therefore, the claim fails to follow the format of "selected from the group consisting of a); b); c); and d)." Examiner requests clarification of the above phrase.

Claim 13 and claims 14-15 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 can be interpreted as a polypeptide selected from the group consisting of "a); b); c); and d) and wherein the polypeptide has dehydrogenase activity" or a polypeptide selected from the group consisting of "a); b); c) and d)". In the latter interpretation, parts of a), b) and c) do not recite the function "dehydrogenase activity". Examiner requests clarification of the above phrase.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (See the rejection of claim 13 under 35 U.S.C. 112, 2nd above)

Claim 13, parts a), b) and c), is drawn to a polypeptide comprising a fragment comprising at least 16 contiguous amino acids of SEQ ID NO:5 and a variant of SEQ ID NO:5, wherein the encoding polynucleotide hybridizes to SEQ ID NOs: 4 or 6 or has at least 90% identity to SEQ ID NOs: 4 or 6 wherein the polypeptides have any function. The claim is directed to a genus of polypeptides having any function or no function. The specification does not contain any disclosure of the function of any polypeptide. The genus of these polypeptides is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated polypeptides are encompassed within the scope of the claim, including partial sequences. The specification discloses only a single species of the claimed genus (i.e. a polypeptide having the amino acid sequence of SEQ ID NO:5 having dehydrogenase activity) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Art Unit: 1652

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel plasmid. Since the plasmid is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmid's sequence is not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plasmid. The specification does not disclose a repeatable process to obtain the plasmid and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of the plasmid should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that if applicants have deposited the plasmid, it must be publicly available. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited

Art Unit: 1652

under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that: 1. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request; 2. upon granting of the patent the strain will be available to the public under the conditions specified in 37 CFR 1.808; 3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and 4. the deposit will be replaced if it should ever become inviable.

Claim 13 is rejected under 35 U.S. 112, first paragraph, because the specification, while being enabling for a polypeptide having an amino acid sequence of SEQ ID NO:5 and having dehydrogenase activity, does not reasonably provide enablement for (A) any or all polypeptides comprising at least 16 contiguous amino acids of SEQ ID NO:5 and (B) a polypeptide comprising any or all variants or mutants of SEQ ID NO:5 wherein the encoding polynucleotide hybridizes to the polynucleotide of SEQ ID NOs: 4 or 6 or has at least 90% identity to SEQ ID NOs: 4 or 6, wherein said polypeptides of (A)-(B) have any function or no function at all and (C) a polypeptide

Art Unit: 1652

having at least 90% identity to SEQ ID NO: 5 having dehydrogenase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. (See the rejection of claim 13 under 35 U.S.C. 112, 2nd above)

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claim 13 encompasses polypeptides comprising fragments comprising at least 16 contiguous amino acids of SEQ ID NO:5, any or all variants of SEQ ID NO:6, wherein the encoding polynucleotide hybridizes to SEQ ID NOs: 4 or 6 under any stringent conditions or has at least 90% identity to SEQ ID NOs: 4 or 6, or any or all variants of SEQ ID NO:5 having at least 90% identity to SEQ ID NO:5. Therefore, the claim is drawn to a genus of polypeptides having any structure.

The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides comprising, variants and mutants broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the

Art Unit: 1652

desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a polypeptide having the amino acid sequence of SEQ ID NO:5 having dehydrogenase activity.

It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides. The specification provides no guidance with regard to the making of variants and mutants of SEQ ID NO:5 or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by the claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claim which encompasses all modifications and fragments of polypeptides of SEQ ID NO:5, comprising any 16 contiguous amino acids of SEQ ID NO:5, having at least 90% sequence identity to SEQ ID NO:5 and wherein the encoding polynucleotide hybridizes to the polynucleotide of SEQ ID NOs:4 or 6 because the specification does not establish: (A) regions of the encoded dehydrogenase structure which may be modified without affecting dehydrogenase activity; (B) the general tolerance of dehydrogenase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The claim also broadly encompasses not only polypeptides having dehydrogenase activity, but polypeptides having any function or having no function. Therefore, the breadth of the claim is much larger than the scope enabled by the specification.

The specification does not teach how to make variants of polypeptide of SEQ ID NO:5 or polypeptides having any function. The function of a polypeptide cannot be predicted from its structure and the specification does not teach how to use polypeptides having any function or having no activity. The quantity of experimentation in this area is extremely large since there is significant variability in the activity of the polynucleotides in the claims. It would require significant study to identify the actual function of the encoded polypeptides and identifying a use for a polypeptide would be

Art Unit: 1652

an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its activity. Even very similar proteins may have very different functions. In the current case, where no specific information is known regarding the function, it is entirely unpredictable what function and activity will be found for the protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the d polypeptides.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polypeptides comprising variants and mutants of SEQ ID NO:5 having any structure and any function. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of variants or mutants of SEQ ID NO:5 having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Ruben et al.

Claim 13 is drawn to polypeptide comprising a fragment of any 16 contiguous amino acids of SEQ ID NO:5 and a variant of SEQ ID NO:5, wherein the encoding polynucleotide hybridizes to the polynucleotide of SEQ ID NOs: 4 or 6.

Ruben et al. (U.S. Patent Pub. No. US 2002/0076705 – form PTO-892) discloses a polypeptide having 100% identity to residues 1-255 of SEQ ID NO:5 of the instant invention (See Sequence Alignment – form PTO-892). The polypeptide of Ruben et al. comprises a polypeptide having at least 16 contiguous amino acids of SEQ ID NO:5 and is encoded by a polynucleotide that hybridizes to SEQ ID NOs: 4 or 5 under any stringent conditions. Therefore, the reference of Ruben et al. anticipates claim 13.

Allowable Subject Matter

Claims 43-45 and 47 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935.


Art Unit: 1652

The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652


Rao Manjunath
Primary Examiner 1652